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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/489,817	01/24/00	RAHMAN M	67459-2022

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EXAMINER	
MCELWAIN, E.	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/489,817	RAHMAN ET AL.	
	Examiner	Art Unit	
	Elizabeth McElwain	1638	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-109* is/are pending in the application.

4a) Of the above claim(s) *45-109* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicant's election with traverse of Group I, claims 36-44, in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the inventions must be independent or distinct and searching the additional inventions must constitute an undue burden on the examiner. In addition, applicants state that the claims are tied together by the single inventive concept that a Brassica genome is transformed with a transparent seed coat gene obtained from a Brassica AA genome, and there is no lack of unity of invention. Applicant further asserts that the method claims must be searched with the product claims, since they depend upon or involve the product claims. This is not found persuasive because the inventions are distinct one from the other and would constitute an undue burden of search and examination on the Examiner, as stated in the last office action. In addition, applicants have argued that there is no lack of unity of invention. However, the present application was not filed under 371, and therefore lack of unity rules do not pertain to the present application. In addition, there is no requirement that method claims be searched and examined with product claims, and the present method claims do not depend from the product claims elected.

The requirement is still deemed proper and is therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicants stated in the description of the drawings (at pages 16-17 of the specification) that several of the drawings provided are photographs. Please note the following.

The drawings are considered to be informal because they fail to comply with 37 CFR 1.84(a)(1) which requires black and white drawings using India ink or its equivalent.

Photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) or (b)(1) is granted permitting their use as formal drawings. In the event applicant wishes to use the drawings currently on file as formal drawings, a petition must be filed for acceptance of the photographs or color drawings as formal drawings. Any such petition must be accompanied by the appropriate fee as set forth in 37 CFR 1.17(i), three sets of drawings or photographs, as appropriate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-44 are indefinite in the recitation of "non-naturally occurring" with regard to a Brassica genome. It remains unclear what is intended by this language, since it could mean that the Brassica is not growing in a cultivated area and it could mean that the genome is isolated from a plant cell. Given the uncertainty regarding the meaning of this terminology, the use of this phrase does not set forth the metes and bounds of the claimed invention, and the specification fails to define or clarify the use of this term.

Claims 36-44 are also indefinite and confusing in the recitation of "transparent seed coat gene", given that the specification asserts that "transparent seed coat gene" may refer to one gene or a number of genes (page 2, lines 20-26). Therefore, the composition of the claimed genome remains unclear, since the claim does not specify how many genes for transparent seed coat are incorporated in the claimed genome.

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps required to transfer the transparent seed coat gene from the AA genome to the CC genome, which would be required prior to chromosome doubling or embryo rescue.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a transformed *Brassica* CC genome comprising an exogenous transparent seed coat gene obtained from a *Brassica* AA genome. However, no written description of said exogenous transparent seed coat gene is provided. Given the lack of written description, it is unclear how one would distinguish an AA

genome seed coat gene from a CC genome seed coat gene. Furthermore, the specification states that the claim language is intended to encompass one or more transparent seed color genes, and the specification also states that *Brassica napus* requires homozygous recessive genes at four loci, and at two loci in *Brassica campestris* (see page 29, lines 5-13 of the specification), thus requiring at least four or two genes, respectively. Yet the claims do not set forth any information regarding the number of genes or the structural features of said genes. No nucleotide sequences have been provided in the specification. Neither do the claims recite any particular functional characteristics of the claimed genomes. There is no indication that the claimed genomes would confer any particular phenotype, including that of a transparent seed coat.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states:

> "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, and given the high level of unpredictability in this art, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either applicants' admitted state of the prior art (pages 9-10 of the specification).

The claims are drawn to a transformed *Brassica* CC genome comprising an exogenous transparent seed coat gene obtained from a *Brassica* AA genome.

Applicants' admitted state of the prior art teaches that Brassica napus plants having AACC genomes and having yellow seeds were known (see pages 9-10 of the specification). The specification teaches that yellow seeds indicate a transparent seed coat (see page 2, lines 16-21, for example). An exogenous transparent seed coat gene obtained from a *Brassica* AA genome would be inherent in the AACC genome, and the specification teaches that "transformed" is intended to mean "made by human intervention" (page 6 of the specification). In addition, while the claimed product may be made by a different method, the product itself is indistinguishable. See MPEP 2113. Therefore, it appears that the claimed Brassica CC genome is the same as those taught in the prior art. However, if the prior art genome differs from that of the claimed genome, then it differs only due to minor morphological variation, which would not confer patentable distinction to the claimed genome. Thus the claimed invention would have been *prima facie* obvious, if not anticipated by applicants' admitted state of the prior art.

Claims 36-44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meng Jinling et al (Euphytica 103(3): 329-333, 1998, Abstract provided).

The claims are drawn to a transformed *Brassica* CC genome comprising an exogenous transparent seed coat gene obtained from a *Brassica* AA genome.

Meng Jinling et al teach that Brassica napus plants having AACC genomes and having yellow seeds were known. The specification teaches that yellow seeds indicate a transparent seed coat (see page 2, lines 16-21, for example), and the specification teaches that "transformed" is

intended to mean "made by human intervention" (page 6 of the specification). In addition, while the claimed product may be made by a different method, the product itself is indistinguishable. See MPEP 2113. Therefore, it appears that the claimed Brassica CC genome is the same as those taught in the prior art. However, if the prior art genome differs from that of the claimed genome, then it differs only due to minor morphological variation, which would not confer patentable distinction to the claimed genome. Thus the claimed invention would have been *prima facie* obvious, if not anticipated by Meng Jinling.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth F. McElwain, Ph.D.
October 5, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600